OCT 24 2001

EXHIBIT 2

MACHNET BV
PO BOX 85444
NL-3508 AK UTRECHT
THE NETHERLANDS

AMERSFOORTSEWEG 24 A
NL-3951 LB MAARN

PHONE +31(0)343 444 355
FAX +31(0)343 444 934
Contact: Abe van der Werf, President

August 1, 2001

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: "Machnet Carotids Coil Array Assembly." (Catalog # PACC-GSXX)
   Classification Name: 90 MOS
   Common/Usual Name: Carotids Coil Array Assembly

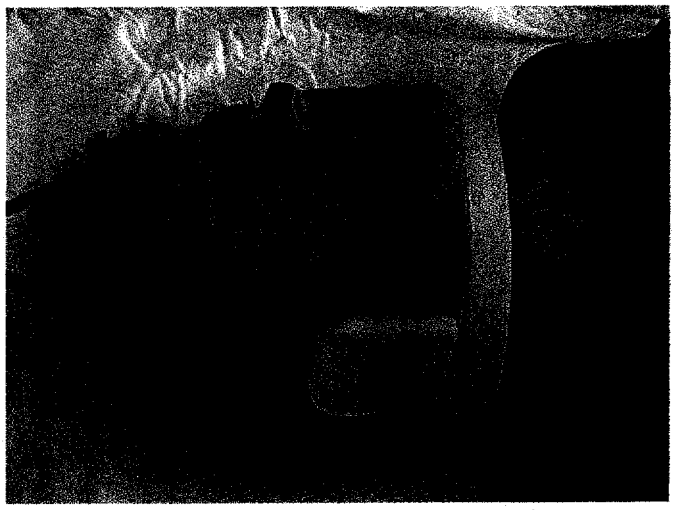
2. Equivalent legally marketed device: This device is similar in design and identical in function to the USA Instruments Hi-Res 9000 Phased Array Carotid Coil K001210.

3. Indications for Use (intended use): To be used in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of Carotid structures that can be interpreted by a trained physician. The Machnet Carotids Coil is designed to provide coverage of the carotid arteries and associated vasculature from the aortic arch through the Circle-of-Willis. Anatomic Regions: Head and Neck Vasculature

4. Description of the device: The Carotids Coil Array Assembly is a receive only coil array which consists of a dual set of coils electrically connected to a quick disconnect box which interfaces the assembly to the MR scanner. Each half of the coil assembly consists of two overlapping coils to buck out the mutual inductance between the coils. Active decoupling is achieved by PIN diodes which turn the coils to a high impedance state at transmit time. A pair of fast switching crossed diodes is installed in each coil segment acting as passive switches detuning the coils to further improve the safety of the Carotids Coil Array Assembly. Each transmission line has so called "bazooka baluns" installed to minimize the outer braiding currents on the coaxial cables. Coil diameter have been chosen to optimize sensitivity at distances to about 35 mm from the coil surface while a sharp cutoff beyond 40 mm from the surface minimizes the noise from volumes

outside the region of interest. This ensures maximum signal ratio from the region of the carotids arteries.

Photo of Product



5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	USA Instruments Hi-Res 9000 Phased Array Carotid Coil K001210.	"Machnet Carotids Coil Array Assembly." (Catalog # PACC-GSXX)
Indications for use	The Hi-Res 9000 Phased Array Carotid Coil is a receive-only phased array RF coil used for obtaining diagnostic images of the carotid arteries and associated vasculature from the Aortic arch through the Circle-of-Willis in Magnetic Resonance Imaging systems. The indications for use are the same as for standard MR Imaging.	SAME
Use with MRI Model	The Hi-Res 9000 Phased Array Carotid Coil is designed for use with the Signa™ (l.5Tesla) MRI scanner manufactured by GE Medical Systems, Inc.	SAME, Signa Advantage 1.5T and 1.0T. Signa Horizon LX 1.5T and 1.0T.
Description	The Hi-Res 9000 Phased Array Carotid Coil is an eight-element phased array receive only coil. The elements and associated circuitry are enclosed in housing made of plastic materials, which are fire rated and have high impact and tensile strength.	SAME except four element.
Function	Receive only	SAME

6. Testing information and Conclusion

In all material respects, the "Machnet Carotids Coil Array Assembly." (Catalog # PACC-GSXX) is substantially equivalent to USA Instruments Hi-Res 9000 Phased Array Carotid Coil (K001210). Testing was performed according to internal company procedures. Test results support the conclusion that actual device performance satisfies the design intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2001

Machnet BV
% Mr. Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K012491
Trade/Device Name: Machnet Carotids Coil Array Assembly
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: August 1, 2001
Received: August 3, 2001

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

j) Indications for Use

510(k) Number K012491

"Machnet Carotids Coil Array Assembly." (Catalog # PACC-GSXX)
To be used in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of Carotid structures that can be interpreted by a trained physician.
The Machnet Carotids Coil is designed to provide coverage of the carotid arteries and associated vasculature from the aortic arch through the Circle-of-Willis.
Anatomic Regions: Head and Neck Vasculature. Nuclei Excited: Hydrogen
The indications for use are the same as for standard imaging:
The GE Signa system is indicated for use as an NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR signal, (2) depend upon NMR parameters (proton density, spin lattice relaxation time Tl, spin-spin relaxation time T2) and (3) display the vasculature of the head and neck regions specifically the carotid arteries and associated soft tissue. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012491